Atty. Dkt. No. 071949-5604



## HE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Buechler et al.

Title:

**USE OF THROMBUS** 

PRECURSOR PROTEIN AND

MONOCYTE

CHEMOATTRACTANT

PROTEIN AS DIAGNOSTIC AND PROGNOSTIC INDICATORS IN

VASCULAR DISEASES

Appl. No.:

10/728,067

Filing Date: December 3, 2003

Examiner:

Unassigned

Art Unit:

## INFORMATION DISCLOSURE STATEMENT

**UNDER 37 CFR §1.56** 

Commissioner for Patents PO Box 1450 Alexandria, Virginia 22313-1450

Sir:

Applicants submit herewith on Form PTO-1449 a listing of the documents cited by or submitted to the U.S. PTO in parent application Serial No. 10/330,696, filed 12/23/2002. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to

**CERTIFICATE OF MAILING** I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450, on the date below. (Signature) (Date of Deposit)

antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

## **TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

## RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

Date

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Barry S. Wilson

Attorney for Applicant Registration No. 39,431

PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Date Submitted: April 14, 2003 (use as many sheets as necessary)

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Complete if Known					
Application Number	10/330,696				
Filing Date	12/23/2002				
First Named Inventor	Kenneth F. Buechler	· · · · · · · · · · · · · · · · · · ·			
Group Art Unit	Unassigned				
Examiner Name	Unassigned				
Attorney Docket Number	071949-5602				

			U	.S. PATENT DOCUMENTS		
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Doo	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	6,156,521		Buechler et al.	12/05/00	
	A2	6,147,688		Clair	11/14/00	
•	A3	6,143,576		Buechler	11/07/00	
	A4	6,113,855		Buechler	09/05/00	
•	A5	6,019,944		Buechler	02/01/00	
	A6	5,985,579		Buechler et al.	11/16/99	
	A7	5,955,377		Maul et al.	09/21/99	
	A8	5,947,124		Buechler et al.	09/07/99	
	A9	5,939,272		Buechler et al.	08/17/99	
	A10	5,922,615		Nowakowski et al.	07/13/99	
	A11	5,885,527		Buechler	03/23/99	
	A12	5,851,776		Valkirs	12/22/98	
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-	A19	5,480,792		Buechler et al.	01/02/96	
	A20	5,453,359		Gargan	09/26/95	
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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. 2See attached Kinds of U.S. Patent Documents. 3Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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Substitute to form 1449 100 O INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Date Submitted: April 14, 2003

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Sheet 2 of 27

	Complete if Known	
Application Number	10/330,696	
Filing Date	12/23/2002	
First Named Inventor	Kenneth F. Buechler	
Group Art Unit	Unassigned	
Examiner Name	Unassigned	
Attorney Docket Number	071949-5602	

				FO	REIGN PATENT DOCUMENT	S		
Examiner Initials*	Cite No. <sup>1</sup>	F Office	oreign Patent Do	cument Kind Code <sup>5</sup> (if known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т <sup>6</sup>
	B1	EPO	999447A1					
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		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examin er Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	C1	Aggarwal et al., "Evaluation of serum lipid profile and cardiac enzyme changes in cerebrovascular accidents," <i>JIMA</i> , 93:331-332 (1995).	
	C2	Akiyama et al., "Changes in serum concentrations of matrix metalloproteins, tissue inhibitors of metallo proteinases and Type IV collagen in patients with various types of glomerulonephritis," Res. Commun. In Mol. Path. and Pharm., 95(2): 115-128 (1997).	
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Examiner Signature	Date Considered	

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INFO	RMATION DISCLO	DSURE 1004	Application Number	10/330,696
STA	TEMENT BY APPL	ICANT 1 TO	首iling Date	12/23/2002
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Sheet 3	of	27	Attorney Docket Number	071949-5602

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examin er Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т <sup>6</sup>
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	Substitute for form	1449B/PTO P	E v		Complete if Known
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	STATEMENT BY A	APPLICANT	7 7004 2	Filing Date	12/23/2002
Date Subn	nitted: April 14,	2006 0	. ` 正	First Named Inventor	Kenneth F. Buechler
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30,000		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
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	C23	Bitsch et al., "A longitudinal prospective study of soluble adhesion molecules in acute stroke," <i>Stroke</i> , 29:2129-2135 (1998).	
	C24	Blankaert et al., "Constitutive release of metalloproteinase-9 (92-kd Type IV collagenase) by Kaposi's sarcoma cells," <i>J. Acquir. Immune Defic. Syndr. Hum. Retrovirol.</i> 18:203-209 (1998).	
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Examiner	Date	
Signature	Consid	lered

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	INFORMATION	ON DISCLO	SURE 1 TON	Application Number	10/330,696
	STATEMENT	r by appl	CANT 1 1 1000	Filing Date	12/23/2002
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Sheet	5	of	27	Attorney Docket Number	071949-5602
Sheet	5	of	27	Attorney Docket Number	071949-5602

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examin er Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т <sup>6</sup>
	C37	Caligiuri et al., "Immune system activation follows inflammation in unstable angina: pathogenetic implications," <i>J.Am. Coll. Cardiol.</i> 32:1295-1304 (1998).	
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•	0.45	Colucciello, S.A., EMR Textbook, pp. 1-23	
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v	C46	Cohen, A.M. et al., "Plasma clearance and tissue distribution of recombinant human platelet-derived growth factor (B-chain homodimer) in rats," J. Surg. Res. 49:447-452 (1990).	
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	C49	D'Astou, M., "Diastolic Heart Failure," Persp. In Cardiology pp. 30-37 (May 2002).	
	C50	Dangas et al., "Correlation of serum lipoprotein(a) with the angiographic and clinical presentation of coronary artery disease," <i>Am. J. Cardiol.</i> 83:583-585 (1999).	

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INFORMATION D	DISCLOS/JRE 6	Application Number	10/330,696	
STATEMENT BY	APPLICANT 1004	Filing Date	12/23/2002	
Date Submitted: April 14	4, 2003	First Named Inventor	Kenneth F. Buechler	
	1	Group Art Unit	Unassigned	
(use as many sheet	ts as necessary)	Examiner Name	Unassigned	
Sheet 6	of 27 TRADE	Attorney Docket Number	071949-5602	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
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	C51	Dao et al., "Utility of B-Type Natriuretic Peptide in the Diagnosis of Congestive Heart Failure in an Urgent-Care Setting," J. Am. Coll. Cardiol. 37:379-85 (2001).	
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-	C60	Doubell, A.F. et al., "Identification and immunolocalisation of annexins V and VI, the major cardiac annexins, in rat heart," Cardiovasc. Res. 27:1359-1367 (1993).	
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	C62	Durany, N. and Carreras, J., "Distribution of phosphyglycerate mutase isozymes in rat, rabbit and human tissues," Comp. Biochem. Physiol. B. Biochem. Mol. Biol. 114:217-223 (1996).	
	C63	Egermayer et al., "Usefulness of D-dimer, blood gas, and respiratory rate measurements for excluding pulmonary embolism," <i>Thorax</i> 53:830-34 (1998).	
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Examiner Signature	Date Considered	,,,,,
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Date Subr	nitted: Anril 14	4, 2003	1 (68 )	irst Named Inventor	Kenneth F. Buechler	
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		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examin er Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	C65	Emsley et al., "Crystal structure of the von Willebrand factor A1 domain and implications for the binding of platelet glycoprotein lb," <i>Journal of Biological Chemistry</i> 273(17): 10396-10401, (1998).	
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•	C67	Endo, S. et al., "Plasma interleukin 8 and polymorphonuclear leukocyte elastase concentrations in patients with septic shock," J. Inflamm. 45:136-142 (1995).	
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	C71	Falciani, M. et al., "Elevated tissue factor and tissue factor pathway inhibitor circulating levels in ischemic heart disease patients," <i>Thromb. Haemost.</i> 79:495-499 (1998).	
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·	C74	Fernandes-Alnemri et al., "CPP32, a novel human apoptotic protein with homology to Caenorhabditis elegans cell death protein Ced-3 and mammalian interleukin-1β-converting enzyme," Journal of Biological Chemistry 269(49): 30761-30764 (1994).	
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	C77	Forssmann et al., "The endocrine heart and natriuretic peptides: histochemistry, cell biology, and functional aspects of the renal urodilatin system," <i>Histochem Cell Biol</i> 110: 335-357 (1998).	
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	C81	Fujii et al., "Hemostasis in spontaneous subarachnoid hemorrhage," <i>Neurosurgery</i> 37(2): 226-234 (1995).	
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	C83	Gaasch, W.H., Diagnosis and treatment of heart failure based on left ventricular systolic or diastolic dysfunction," <i>JAMA</i> 271:1276-80 (1994).	
	C84	Gabay et al., "Interleukin 1 receptor antagonist (IL-1Ra) is an acute-phase protein," <i>J. Clin. Invest.</i> 99(12): 2930-2940 (1997).	
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	C90	Gensini, G.F. et al., "Increased protein C and fibrinopeptide: a concentration in patients with angina," <i>Thromb. Res.</i> 50:517-525 (1988).	
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	C93	Ghanem, H. et al., "Increased low density lipoprotein oxidation in stable kidney transplant recipients," Kidney Int. 49:488-493 (1996).	
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•	C100	Goto et al., "Enhanced shear-induced platelet aggregation in acute myocardial infarction," Circulation 99:608-613 (1999).	
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	C103	Gurfinkel, E. et al., Importance of thrombosis and thrombolysis in silent ischaemia: comparison of patients with acute myocardial infarction and unstable angina," <i>Br. Heart J.</i> 71:151-55 (1994).	
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	C115	Hoffmeister, H.M. et al., "Alterations of coagulation and fibrinolytic and kallibrein-kinin systems in the acute and postacute phases in patients with unstable angina pectoris," <i>Circulation</i> 91:2520-27 (1995).	

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7, 3	C116	Hoffmeister, H.M. et al., "Correlation between coronary morphology and molecular markers of fibrinolysis in unstable angina pectoris," <i>Atherosclerosis</i> 144:151-157 (1999).	
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•	C124	lizasa, T. et al., "Elevated levels of circulating plasma matrix metalloproteinase 9 in non-small cell lung cancer patients," Clin., Cancer Res. 5:149-153 (1999).	
	C125	Ikeda, H. et al., "Increased soluble form of P-selectin in patients with unstable angina," Circulation 92:1693-1696 (1995).	
	C126	Ikeda, H. et al., "Soluble form of P-selectin in patients with acute myocardial infarction," Coron. Artery Dis. 5:515-518 (1994).	
	C127	Isgro et al., "A predictive parameter in patients with brain related complications after cardiac surgery," Eur. J. Cardiothorac. Surg. 11: 640-644 (1997).	
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	C130	James, T., "The variable morphological coexistence of apoptosis and necrosis in human myocardial infarction: significance for understanding its pathogenesis, clinical course, diagnosis and prognosis," <i>Coron. Artery Dis.</i> 9:291-307 (1998).	
	C131	Janoff, A., "Elastase in tissue injury," Annu Rev Med 36:207-216 (1985).	
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•	C133	Jimenez, W. et al., "Nitric oxide production and inducible nitric oxide synthase expression in peritoneal macrophages of cirrhotic patients," <i>Hepatology</i> 30:670-676 (1999).	
	C134	Johnson et al., "Activation of matrix-degrading metalloproteinases by mast cell proteases in atherosclerotic plaques," <i>Arterioscler. Thromb. Vasc. Biol.</i> 18:1707-1715 (1998).	
	C135	Johnsson et al., "Markers of cerebral ischemia after cardiac surgery," J. Cardiothorac. Vasc. Anesth. 10: 120-126 (1996).	
	C136	Johnston, G.I. et al., "Structure of the human gene encoding granule membrane protein-140, a member of the selectin family of adhesion receptors for leukocytes," J. Biol. Chem. 265:21381-21385 (1990).	
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Date Submitted	Арш 14,	2003	AFR.	Group Art Unit	Unassigned
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	C154	Kohno, "Serum marker KL-6/MUC1 for the diagnosis and management of interstital pneumonits," <i>J. Med. Invest</i> . 46:151-58 (1999).	
	C155	Koller et al., "Clinical value of monitoring eosinophil activity in asthma," Arch. Dis. Childhood 73:413-7 (1995).	
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	C157	Kosar, F. et al., "Plasma leukocyte elastase concentration and coronary artery disease," Angiology 49:193-201 (1998).	
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	C160	Krause, E.G. et al., "Glycogen phosphorylase isoenzyme BB in diagnosis of myocardial ischaemic injury and infarction," Mol. Cell Biochem. 160-161:289-295 (1996).	
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·	C163	Krupinski, J. et al., "Protein kinase C expression and activity in the human brain after ischaemic stroke," <i>Acta Neurobiol. Exp. (Warz)</i> 58:13-21 (1998).	
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	C221	Nishiyama et al., "Simultaneous elevation of the levels of circulating monocyte chemoattractant protein-1 and tissue factor in acute coronary syndromes," <i>Jpn. Circ. J.</i> 62:710-712 (1998).	
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	C234	Pellegatta, F. et al., "Soluble E-selectin and intercellular adhesion molecule-1 plasma levels increase during acute myocardial infarction," J. Cardiovasc. Pharmacol. 30:455-460 (1997).	
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